

(c) REMARKS

This application has been reviewed in light of the Office Action dated January 15, 2010. Claims 1, 2, 4, 11, 14, 25 and 26 are presented for examination, with claim 1 being in independent form. Claim 1 has been amended to better define the intended invention. Support for the amendment may be found on page 5, line 34 through page 6, line 20 of the subject specification as filed. No new matter has been added. Favorable reconsideration is requested.

Claims 1, 2, 4, 11, 14, 25 and 26 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,994,329 (Daifotis) in view of either U.S. Patent No. 4,817,819 (Kelly) or U.S. Patent No. 5,265,728 (Allendorf). Applicants respectfully traverse the rejections.

Prior to addressing the grounds of rejection, Applicants wish to briefly review certain features and advantages of the present invention. The invention is related to a kit for promoting the proper sequential and continuous oral administration of a bisphosphonate and an accompanying nutrient over a 28 day period of time. The kit contains 4 unit doses of the bisphosphonate, wherein each dose is to be given once a week; 24 unit doses of a nutrient selected from the group consisting of calcium, vitamin D, calcium and vitamin D, and a combined unit dose of calcium and vitamin D, and unit doses of calcium are about 400 mg to about 1500 mg of elemental calcium per day and unit doses of vitamin D are about 100 IU to 10,000 IU per day; and a blister card containing the unit doses, which are arranged in order of their use across the blister card. Combining administration of an active with a nutrient increases patient compliance and maximizes the benefits achieved by the treatment. Specifically in regard to calcium, patients are often instructed to take a calcium supplement. However, bisphosphonate and calcium should not

be taken at the same time because the calcium interferes with the absorption of the active.

Page 2, lines 28-38. By using the kit of the present invention, the patient takes the accompanying nutrient on days when she is not taking the active, thereby avoiding any problems associated with simultaneous dosing. *Id.*

Daifotis is directed toward a method for inhibiting bone resorption employing a bisphosphonate according to a continuous schedule. As acknowledged by the Examiner, Daifotis fails to teach or suggest a blister pack as disclosed in the present invention. In addition, while Daifotis discloses the use of a bisphosphonate according to varying dosing schedules, it fails to specifically recite or show, by way of example, any regimens administering doses of a nutrient. At column 13, lines 61-65, Daifotis discloses a list of possible additional dosages to the kit, including calcium, as a potential memory aid, however, it fails to specifically identify vitamins, or, more specifically, vitamin D, or to appreciate the benefits achieved by taking a nutrient while eliminating the problems of simultaneous dosing of a nutrient and bisphosphonate, as disclosed in the present invention and explained above. Further, Daifotis fails to offer any guidance as to the amount of calcium or other nutrient that might be administered in unit doses in the kit. Daifotis fails to disclose or suggest the administration of unit doses of calcium, vitamin D, or combinations thereof, wherein the unit dose of calcium is about 400 mg to about 1500 mg of elemental calcium per day and the unit dose of vitamin D is about 100 IU to 10,000 IU per day, as is recited in the presently amended claims. Therefore, for all of the reasons set forth above, Applicants submit that Daifotis fails to render the presently claimed invention obvious.

Kelly and Allendorf fail to remedy the deficiencies of Daifotis. Both Kelly and Allendorf are cited by the Examiner for teaching blister packs for storing and

dispensing tablets. However, neither of the references teach administration of unit doses of an accompanying calcium, vitamin D, or a nutrient of any kind. They merely teach that seven tablets in the blister pack might be a placebo or non-active tablet. Further, there is clearly no disclosure or suggestion of the amount of calcium, or vitamin D to be administered in the unit doses as presently claimed, e.g, about 400 mg to about 1500 mg of elemental calcium per day and about 100 IU to 10,000 IU per day. Therefore, Applicants respectfully submit that Daifotis, Kelly and Allendorf, in any permissible combination, fail to render the present invention obvious and respectfully request withdrawal of the § 103 rejections.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue is earnestly requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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